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W81XWH-14-1-0008

TITLE:
"Web-PE: Internet-Delivered Prolonged Exposure Therapy for PTSD

PRINCIPAL INVESTIGATOR:
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CONTRACTING ORGANIZATION:
University of Pennsylvania
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PREPARED FOR:
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14. ABSTRACT

 It is urgent to make evidence-based treatments (EBTs) for military personnel readily accessible in order to meet the growing demand for effective and efficient treatment for posttraumatic stress disorder (PTSD) in a timely manner. Web-treatments represent an innovative way to overcome barriers to accessing care. The purpose of this randomized controlled trial is to compare the efficacy of 10 sessions of a web-version of Prolonged Exposure (PE), "Web-PE," delivered over 8-weeks to 10 sessions of Present Centered Treatment (PCT) delivered over 8-weeks by a therapist in 120 active duty military personnel with PTSD. Up to 170 individuals will be consented to obtain data from 120 for analysis. Participants will be assessed at pre-treatment, mid-treatment, and 1-, 3- and 6-months after treatment completion.

15. SUBJECT TERMS
Prolonged Exposure, combat, psychological treatment, military, psychotherapy, trauma, posttraumatic stress, posttraumatic stress disorder

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INTRODUCTION

It is urgent to make evidence-based treatments (EBTs) for military personnel readily accessible in order to meet the growing demand for effective and efficient treatment for posttraumatic stress disorder (PTSD) in a timely manner. Effective EBTs for PTSD are available, but barriers to accessing care can deter military personnel from receiving treatment. Web-treatments represent an innovative way to overcome these barriers. The efficacy of previously developed web-treatments for PTSD appear promising, however, they are not based on treatment protocols with strong empirical support for their efficacy. No study to date has examined web-treatment of PTSD using a well-established treatment program. An important unanswered question is whether moving from the traditional, costly, access-limiting, therapist-delivered format of an effective treatment to a more accessible, cost-effective, web-format will have an impact on treatment efficacy.

The purpose of this randomized controlled trial is to compare the efficacy of 10 sessions of a web-version of Prolonged Exposure (PE), "Web-PE," delivered over 8-weeks to 10 sessions of Present Centered Treatment (PCT) delivered over 8-weeks by a therapist in 120 active duty military personnel with PTSD. Up to 170 individuals will be consented to obtain data from 120 for analysis. Participants will be assessed at pre-treatment, mid-treatment, and 1-, 3- and 6-months after treatment completion.

KEYWORDS
Prolonged Exposure, combat, psychological treatment, military, psychotherapy, trauma, posttraumatic stress, posttraumatic stress disorder

ACCOMPLISHMENTS

<u>What were the major goals and accomplishments of the project?</u>

Phase 1 Specific Aims:
1) Develop a Web-PE program that receives high ratings of ease of use, acceptability, comprehension of program content and functionality, and overall satisfaction by members of the expert advisory board.
      Goal 1: Finalize detailed outline of Web-PE. Status: **Completed**.
      Goal 2: Complete beta-testing of Web-PE. Status: **Completed (see summary below)**.
      Goal 3: Complete development of full Web-PE program. Status: **Completed**.
      Goal 4: Complete Web-PE therapist training. Status: **Completed**.
      Goal 5: Obtain STRONG STAR-CAP Data and Safety Monitoring Board (DSMB) approval on the protocol. Status: **Completed**.
      Goal 6: IRB approval at UTHSCSA, BAMC, UPenn, and HRPO. Status: **50% (BAMC and HRPO pending).**
2) Pilot Web-PE with 6 active-duty military personnel seeking treatment for PTSD at Fort Hood, TX to assess change in PTSD severity from pre- to post-treatment.
      Goal 1: Recruit and pilot Web-PE with 5 clinical cases. Status: 2**0% (Cases have been screened and one participant has begun treatment)**.

Phase II Specific Aims:

1) Test whether Web-PE is a more efficacious treatment for PTSD than PCT by comparing participants randomized to Web-PE (n=60) versus those randomized to PCT (n=60) on the following outcomes: PTSD severity and diagnostic status, depression, anger, and other frequently co-occurring problems.

        Goal 1: Complete participant enrollment. Status: **0%.**
        Goal 2: Report study findings. Status: **0%.**

Summary of beta-testing:
Participants: Military personnel at Fort Hood, TX (N = 10) expressing interest in beta-testing Web-PE.
Method: Feedback on the Web-PE prototype was sought from members of an expert advisory board and 10 military personnel. Beta-testing participants reviewed the Web-PE prototype.
Measure: The Satisfaction and Usability Survey, a 16-item survey that assessed ease of use, helpfulness, and overall satisfaction.
Scores range from 1 (Not enjoyable/helpful/relevant/likely) to 5 (Extremely enjoyable/helpful/relevant/likely). Sample items: "How well did Web-PE hold your interest?", "How helpful do you imagine this tool will be to individuals with PTSD?"
Results: (N = 6); Mean: 3.98 (SD: 0.73)
Conclusion: Beta-testing indicated that the Web-PE prototype was perceived as very enjoyable to use, helpful, and relevant. Verbal feedback from participants resulted in several helpful suggested revisions, including changing specific visual aspects of the program (e.g., images, colors) and word choice (e.g., using lay language in place of more technical terms), which were subsequently implemented.

What opportunities for training and professional development has the project provided?
Nothing to report at this time.

How were the results disseminated to communities of interest?
Nothing to report at this time.

What do you plan to do during the next reporting period to accomplish the goals?
- Obtain BAMC deferral to UTHSCSA and HRPO IRB approvals.
- Continue pilot-testing Web-PE with 6 clinical cases
- Site visit to Fort Hood for project kick-off meeting with all key personnel (scheduled for 16 October 2015).
- Maintain regulatory approvals

IMPACT
Nothing to report at this time.

CHANGES/PROBLEMS

Changes in approach and reasons for change:

1. Sample size increase. The revised power analysis, based on the CAPS-5 score, changed the sample size required for clinical significance from 100 to 120. We plan to consent up to 170 participants until data is obtained from 120 for analysis. In light of other design changes (e.g., a change in the assessment schedule that decreased the number of independent evaluator assessments), we are confident that we can treat 120 with the approved budget.
2. Decrease the number of clinical cases to pilot Web-PE. We originally planned to pilot Web-PE with 12 patients, but are now planning to recruit 6. The reason for this is that there are now two study therapists instead of three, and the clinical supervisors, therapists, and other study team members agreed that three cases each would be more than sufficient to pilot the program.
3. With knowledge and support from the MOMRP, we are now collaborating with Sheila Rauch, PhD who was funded by the Consortium to Alleviate PTSD (CAP) to examine the role of specific candidate biomarkers. Dr. Rauch aims to: 1) identify specific changes in neuroendocrine and neurosteroid patterns that "track" PTSD symptom changes following effective treatment, 2) examine the specificity of PE-induced neuroendocrine and neurosteroid changes by directly comparing patterns across PE-Web and PCT, and 3) examine whether treatment response related changes in these peripheral biomarkers are directly associated with treatment changes. We intend that one human subjects research protocol reviewed by the UTHSCSA IRB will be required to complete the Statements of Work for both this project as well as Dr. Rauch's project. With the UTHSCSA IRB review and approval we will request that both the Brooke Army Medical Center (BAMC) IRB that reviews for the Carl R. Darnall Army Medical Center (CRDAMC) and that the University of Pennsylvania (UPenn) IRB will defer their reviews to UTHSCSA using an Institutional Agreement for IRB Review (IAIR). We anticipate that the Emory University, VA Ann Arbor Healthcare System, and Duke University investigators who will be analyzing the samples collected as part of Dr. Rauch's project will receive a non-human subjects research determinations from their institutions. With these approvals in place, we will request that HRPO review and approve the study.

Actual or anticipated problems or delays and actions or plans to resolve them:
Waiting for BAMC and HRPO IRB approval; no action required.

Changes that had a significant impact on expenditures:
Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents:
Nothing to report.

PRODUCTS
Nothing to report.

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

University of Pennsylvania Staff

Name: Carmen P. McLean, Ph.D.
Project Role: Overall PI
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3
Contribution to Project: Dr. McLean has coordinated the development of study regulatory materials and has overseen the development of the Web-PE program (NogginLabs).

Name: Edna B. Foa, Ph.D.
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Dr. Foa has assisted with coordination and development of study materials including the Web-PE program.

Name: Hallie (Avizad) Tannahill, B.A.
Project Role: Research Assistant (UPenn)
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 4
Contribution to Project: Ms. Tannahill has assisted with preparing the research protocol and IRB amendments.

Consultants

Name: NogginLabs
Project Role: Web Development Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: NogginLabs has completed the development of the Web-PE program in close consultation with the study PI.

UTHSCSA Subcontract

Name: Alan Peterson, Ph.D.
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Dr. Peterson has provided direct leadership and management of all aspects of STRONG STAR activity associated with the study.

Name: Stacey Young-McCaughan, RN, Ph.D.
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1

Contribution to Project: Dr. Young-McCaughan has overseen development of study regulatory materials and provided consultation regarding IRB review processes to Dr. McLean.

Name: Jim Mintz, Ph.D.
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Dr. Mintz has overseen development of the study database.

Name: Katherine Dondanville, Psy.D.
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Dr. Dondanville has provided consultation regarding standard clinical practices at Ft. Hood to assist in preparing regulatory materials for IRB review.

Name: Brooke Fina, LCSW
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3
Contribution to Project: Ms. Fina has assisted with developing the final Web-PE program and has completed training to be a Web-PE and PCT therapist.

Name: Brittany Hall-Clark, Ph.D.
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3
Contribution to Project: Dr. Hall-Clark has assisted with developing the final Web-PE program and has completed training to be a Web-PE and PCT therapist.

Name: Raymond Aguilar, B.S.
Project Role: Data Core Supervisor
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Mr. Aguilar has overseen the migration of the Web-PE program to the STRONG STAR database, and has created and maintained a program website. He has also facilitated communication between investigators and the database staff.

Name: Scott Pleyte, MBA

Project Role: Programmer
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Mr. Pleyte has coordinated the migration of the Web-PE program to the STRONG STAR database, and has created and maintained a program website.

Name: Kevin Muenzler
Project Role: Programmer
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Mr. Muenzler has created and maintained the centralized databases for the project, and has supervised his staff to update and maintain the database as necessary on the STRONG STAR server.

Name: Gary Lemly
Project Role: Hardware Support Technician
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Mr. Lemly has provided assistance with database troubleshooting and programming.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
Nothing to report at this time.

What other organizations were involved as partners?
Department of Psychiatry and Behavioral Sciences, Emory University
Carl R. Darnall Army Medical Center at Fort Hood, Texas
University of Texas Health Science Center at San Antonia

SPECIAL REPORTING REQUIREMENTS
See attached Quad Chart.

APPENDICES
None.